DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 9, 2014

Remendium Labs, LLC
Yolanda Lorie
Chief Operating Officer
340 East Parker Road
Baton Rouge, LA 70803

Re: K133990
Trade/Device Name: Ieva Rehabilitative Positional Device
Regulation Number: 21 CFR§ 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: September 9, 2014
Received: September 10, 2014

Dear Yolanda Lorie,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5. Indications for Use Statement

510(k) Number (if known): Original 510(k) Submission - K133990

Device Name: Ieva Rehabilitative Positional Device

Indications for Use:

The Ieva Pelvic Floor Trainer is intended for the purpose of rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild-moderate urge incontinence in women. This device interacts with the user via smart phone technology.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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510(k) Summary

Submitter's name and address:	Remendium Labs, LLC 340 East Parker Road Baton Rouge, LA, USA 70803
Contact person:	Yolanda Lorie, Chief Operating Officer Remendium Labs, LLC 340 East Parker Road Baton Rouge, LA, USA 70803 Phone: +1-386-717-4360 eMail: ylorie@mac.com
Date Summary was prepared:	December 20, 2013
Trade/Proprietary Name:	Ieva Rehabilitative Positional Device
Common/Usual Name:	Pelvic Muscle Exerciser
Classification Name:	Perineometer
Product Code:	HIR
Regulation Number:	21 CFR 884.1425
Device Classification:	Class II
Predicate Devices	InCare Pressure Biofeedback Vaginal Probe (K013653)

1.1 Device Description

The Ieva Rehabilitative Positional Device is a device specifically designed to facilitate Kegel exercise training of women with urinary incontinence by physicians and associated therapists. The device is designed to be discreet and simple to use. Each Ieva is intended to be used repeatedly by a single patient. The device is designed to be used vaginally.

The RPD hardware consists of the training device itself and an associated battery powered electronics box. The training device has a biocompatible, colored silicone covering which isolates the motion electronics from the environment. The patient inserts the training device in her vagina before commencing Kegel exercises and wirelessly connect the RPD to the smartphone. The training device remains in place during the Kegel exercises. This device can be washed before and after exercise by the patient.

A smartphone, with the appropriate app, is used to connect wirelessly to the RPD and shows the angle of the pelvic floor and the relative motion. This enables the user to visualize the Kegel exercise she is being trained on. The app will carry the information recorded by the patient on her smartphone or tablet. Such information will then connect to a website for the patient or health care provider to store information and retrieve information related to the use of the RPD.

A website is provided for access by the patient, health care provider and insurance company. This website provides utilities for the patient, the health care provider and the insurance company. For the patient the website provides on-going tracking of performance—showing improvement in the patient's Kegel exercises when using the RPD. The health care provider shall have access for monitoring their patients' performance.

One RPD is intended for only one patient per device and there is no applicable shelf life for this device.

1.2 Intended Use

The Ieva Pelvic Floor Trainer is intended for the purpose of rehabilitation and training of weak pelvic floor muscles for the treatment of stress, mixed and mild-moderate urge incontinence in women. This device interacts with the user via smart phone technology.

1.3 Technological Characteristics and Substantial Equivalence

The Ieva Rehabilitative Positional Device consists of two major components: the vaginal device and an electronics box.

As shown in Table 1, the Ieva has similar technical characteristics as the predicate devices, and any differences do not affect safety or effectiveness.

The InCare device uses the pressure applied to the outside of the probe as the parameter to be reported to the patient to reflect the strength of the Kegel exercise being performed. In practice, the pressure-based devices can reflect the pelvic floor contraction, the vaginal wall contraction or both. If the patient contract's her vaginal wall, the pressure device may read the contraction as a valid Kegel, giving a false impression during training. The set of muscles contracting is therefore important. Anatomically, when the vaginal walls contract, the center line of the vagina does not significantly move, whereas, during a properly performed Kegel, the pelvic floor raises, bending the vagina, and by association, the urethra. The leva RPD uses the accelerometers to determine the relative bend in the probe, between the vaginal entrance and the deep vagina. In this way the leva displays the relative strength of the Kegel by showing the bend and uplift of the pelvic floor. A Kegel with only vaginal wall contraction will show little or no response. Thus the parameter measured by the devices differs, however the intent of displaying the relative intensity of the Kegel exercise is the same.

Each of these sensor systems provides the physician with an objective measure to assist in the training of a patient and the monitoring of the progress of the physician's treatment program.

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Table 1 Ieva Device and Predicate Comparison

Device	Submitted Device	Predicate
	leva	InCare Pressure Biofeedback Vaginal Probe
Manufacturer	Remendium Labs, LLC	Hollister Incorporated
K Number	TBD	K013653
Common or Usual Name	Pelvic Muscle Exerciser	Pelvic Muscle Exerciser
Regulation Number	884.1425	884.1425
Product Code	HIR	HIR
Intended Use	The 'leva' Pelvic Floor Trainer is intended for the purpose of rehabilitation and training of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women. This device interacts with the user via smart phone technology.	The InCare Pressure Biofeedback Vaginal Pressure Probe and Anal Pressure Probe are intended to provide pressure biofeedback from pelvic musculature for the purpose of rehabilitation of weak pelvic floor muscles in the treatment of urinary incontinence.
Purpose	Vaginal exerciser/trainer	Vaginal exerciser/trainer
Principle of Operation	Provides indication of relative intensity of pelvic floor muscle contraction	Provides indication of relative intensity of pelvic floor muscle contraction
Muscle Stimulation	No	No
Parameter	Relative position of device	Pressure applied to device
Target Population	Women with mild incontinence	Women with mild incontinence
Anatomical Site	Vagina	Vagina
Single Patient Device	Yes	Yes
Reusable	Yes	Yes
Sterile	Clean, non-sterile	Clean, non-sterile
Information Display	Graphical and numeric based on applied bending, anatomical overlay	Graphical based on applied pressure
Probe Covering Material	Silicone	Silicone
Biocompatibility	ISO 10993-1	ISO 10993-1
Instructions for Use	Manual	Manual
Cleaning	Washable	Washable

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1.4 Safety evaluation

The Ieva Rehabilitative Positional Device has been tested and found to conform to the requirements of IEC 60601-1:2005 (3rd Edition), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests, and IEC 60601-1-11 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. The results of these tests indicate that the device is safe for the intended use.

1.5 Summary of Effectiveness Data

The Ieva Rehabilitative Positional Device has been tested against all of the input requirements, including life flex testing, packaging testing and usability testing. The results of these tests indicate that the device is effective for the intended use.

The testing included: hardware verification testing, electromagnetic compatibility testing, safety evaluation and testing, software validation testing, useability testing, packaging testing, biocompatibility evaluation, and traceability analysis.

As part of the hardware verification testing, Ieva systems were subjected to testing to ensure that the design device conforms to the requirements of the Marketing Specification, Product Specification and System Hazards Analysis.

Specific device testing included: measurement and inspection of engineering drawings and specifications, testing of the ability of the cable and vaginal device to withstand pulling for over 1,460 cycles (expected lifetime of the device), cleaning of the device over 1,460 times (expected lifetime of the device), and +/- 20° bending of the device for over 1,40 cycles (expected lifetime of the device).

Software validation was performed and successfully completed with no outstanding anomalies. Testing included examination of security of communications between the system components.

Useability testing was performed using lay volunteers and comprised: reading the Instructions for Use and Quick Start Guide, setting up the system, using the system correctly, performing a mock Kegel, interpreting the user interface, cleaning, storage, and disposal. All participants successfully completed all testing.

The packaging with a complete Ieva System enclosed was subjected to ISTA 2A-2011 “Partial Simulation Performance Test Procedure for Packaged Products 150 lb (68 kg) or Less” testing, which included: Atmospheric Preconditioning, Atmospheric Conditioning, Compression, Initial Random Vibration, Impacts, Final Random Vibration. The packaging was found to adequately protect the device during shipping and storage.

Biocompatibility evaluation was performed to satisfy ISO 10993-1 and FDA requirements. All patient contacting materials have been tested and passed cytotoxicity, sensitization and irritation or intracutaneous reactivity protocols.

A traceability analysis was also performed, tracing all the requirements from the Marketing Specification, Product Specification and System Hazards Analysis through to the final test reports and results. All requirements for the device have successfully passed testing.

1.6 Conclusion

The Ieva Rehabilitative Positional Device has been shown to be safe through extensive bench testing, to have a intuitive and usable interface and is substantially equivalent to its predicate device: InCare Pressure Biofeedback Vaginal Probe (K013653); and that the technical differences between the devices do not raise any new questions of safety or effectiveness